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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/734,786	12/11/2000	Norimitsu Saito	312762002400	4706

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EXAMINER
SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
1636	14

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/734,786	SAITO ET AL.	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,11,13-15,17 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,11,13-15,17 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 January 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1☐ Certified copies of the priority documents have been received.

2☐ Certified copies of the priority documents have been received in Application No. _____.

3☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *13*.
4)☐ Interview Summary (PTO-413) Paper No(s). _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☒ Other: *Notice to Comply*.

DETAILED ACTION

This Office Action is a response to the "Amendment under 37 C.F.R. § 1.111" filed 8 January 2003 (Paper No. 12) in reply to the Non-Final Office Action mailed 3 October 2002 (Paper No. 10). Claims 1-21 were considered in Paper No. 10. Claims 11, 15, 17 and 19 were amended and claims 9, 10, 12, 16, 18, 20 and 21 were canceled in Paper No. 12. Claims 1-8, 11, 13, 14, 15, 17 and 19 are pending and under consideration herein.

Drawings

The formal drawings submitted 8 January 2003 (Paper No. 11) are approved.

Specification

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825).

Applicant requests clarification of the notation at the top of page 4 regarding sequence disclosures in the specification. The specification was objected to because sequence is discussed therein (e.g. at pages 11, 15 and 16) that is not accompanied by a sequence identifier number referring back to the Sequence Listing.

Response to Amendment

Rejection of claims 9, 10, 12, 16, 18, 20 and 21 is rendered moot by cancellation of the claims in Paper No. 12.

Claim Rejections - 35 USC § 112

Claims 1-8, 11, 13, 14, 15, 17 and 19 stand rejected under 35 U.S.C. 112, first paragraph, as lacking enablement for the reasons set forth in Paper No. 10 and herein below in the "Response to Arguments".

Claim Rejections - 35 USC § 102

Rejection of claims 15 and 17 under 35 U.S.C. 102(b) as being anticipated by Li *et al.* (1997) U.S. Patent No. 5,641,508 is withdrawn. Li *et al.* does not teach or suggest a method wherein the histoculture is treated with collagenase.

Rejection of claims 11, 13 and 17 under 35 U.S.C. 102(b) as being anticipated by either one of Poston *et al.* (1998) *J Thoracic Cardiovasc. Surg.* 116:386-396 or Chapelier *et al.* (1996) *Hum. Gene Ther.* 7:1837-1845. The cited art does not teach or suggest a method wherein the histoculture is treated with collagenase.

Response to Arguments

Claim Rejections - 35 USC § 112

In response to the rejection of claims 1-21 in Paper No. 10 as lacking enablement on the grounds that the specification fails to provide an enabled use for the claimed method, Applicant argues that the methods of the invention are simply tools. They offer ways to modify tissues in intact animals for whatever purpose. Applicant points to Example 2 to illustrate the use of the method to label specific tissues in an experimental animal and states that, in that context, the method of the invention amounts to a research tool. This argument has been fully considered but is not found persuasive because it fails to provide a specific example of a real-world utility for the invention. Modification of tissues, in and of itself, is not useful unless the modified tissues have patentable utility; that is, provide immediate benefit to the public. The specification contemplates using the claimed method therapeutically to effect the growth or quality of hair or to produce immunogens for immunization (page 4, second full paragraph; paragraph bridging pages 7 and 8; and paragraph bridging pages 9 and 9), or for research "to generate modified subjects such that the effect of the proteins introduced by this gene therapy method can be evaluated" (paragraph bridging pages 8-9). For reasons of record in Paper No. 10, the skilled artisan would clearly be unable to use the claimed method to treat or immunize an individual without engaging in undue experimentation; and, with regard to utility as a research tool, the purpose of the research described above and in Example 2 is to test the operability of the invention and to further develop the invention for therapeutic applications. Thus, the asserted utility amounts to studying the properties of the claimed method or improving the invention, which does not constitute a patentable utility (see the Revised Interim Utility Guidelines

Training Materials, available at www.uspto.gov or

http://www.uspto.gov/web/offices/pac/utility/utilityguide.pdf).

Applicant also suggests that the methods may simply serve to introduce nucleic acids as *per se* pharmaceuticals. This argument is not persuasive because Applicant does not point to any teachings in the specification regarding the introduction of nucleic acids as *per se* pharmaceuticals or teachings that provide a specific and substantial utility for introduction of nucleic acids as *per se* pharmaceuticals.

Finally, Applicant argues that the methods are enabled even if gene therapy is the only conceivable utility or purpose for the invention methods because the problem of gene delivery is the precise problem that the methods of the invention solve. Applicant argues, "[i]f there are additional problems which the invention does not solve, others are entitled to claim those" (paragraph bridging pages 5 and 6). This argument is not persuasive because, until the additional problems are solved, the invention has no patentable utility. As pointed out in the previous office action, it is relatively routine in the gene transfer art to achieve expression at non-therapeutic levels; however, without specific guidance and direction, it is unpredictable whether one will achieve expression of a particular molecule at levels *sufficient for a therapeutic effect*. The only patentable utility contemplated in the specification is gene therapy, but there is nothing in the disclosure to indicate that a therapeutic effect could be obtained using claimed method without additional experimentation. For reasons of record, the amount of experimentation required would clearly be beyond what is considered routine in the art; therefore, the disclosure fails to enable the skilled artisan to use the invention without first engaging in undue experimentation.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER

dms
March 20, 2003